The rejection is traversed on the basis that, on its face, the passage in Hauske cited by the Examiner does not refer to the treatment of animals. The first sentence in the passage referred to by the Examiner is reproduced as follows:

> For in vitro use for topical application, it will usually be convenient to prepare pharmaceutical compositions, in which the compound of formula III is combined with a pharmaceutically acceptable carrier or diluent, for example in the form of ointments and creams. [Hauske, column 9, lines 24-29]

In particular, attention is directed to the term "in vitro use". Webster's New Collegiate Dictionary (Copyright 1981, Published by G&C Merriam, Springfield, Massachusetts) defines "in vitro" as "outside the living body and in an artificial environment". It is submitted that, by the use of this phrase, Hauske was clearly excluding in vivo use, i.e., in animals. Just as clearly, the ointments and creams Hauske alluded to were for in vitro uses, such as the in vitro examples he gives in the same paragraph - - sterilization purposes including sick room utensils, water treatment, slime control, paint and wood preservation. It makes no sense to talk about "in vitro" uses as including animal applications, and Hauske is unmistakably disclosing only in vitro uses in the passage cited by the Examiner. As further support that Hauske is not disclosing anything relating to animal or human applications at column 9, lines 24-35, it is noted that Hauske talks separately about in vivo applications at column 9, line 60 to column 10, line 25. Most of that discussion applies to tablets, although Hauske also discloses parenteral use as well. Nowhere does Hauske mention topical application in his disclosure relating to such in vivo use.

Thus, Applicant maintains that the section of Hauske (column 9, lines 24-35) does not apply to in vivo topical use, and by its express use of the term "in vitro", to modify the utilities recited in that passage, can not. That section, on its face, does not disclose anything relating to topical eye administration. Withdrawal of the rejection is accordingly respectfully requested.

Claims 4-6 stand rejected under 35 USC 102(b) as anticipated or, in the alternative, under 35 USC 103(a) as obvious over Bailey, Thylefors, or Hauske et al.

The rejection is traversed for the reasons which follow. As regards Hauske, anticipation cannot lie, inter alia, because Hauske does not disclose azithromycin, to which Applicants' claims are limited. Rather Hauske discloses derivatives which are related to azithromycin in that they are azalides. Regarding obviousness, Applicant's invention relating to topically applying azithromycin to the eye cannot be obvious from Hauske either. As noted above, Hauske does not disclose or suggest topically

applying azithromycin to the eye, and it is so well accepted as not to require citation that the prior art must suggest making a modification or motivating the ordinarily skilled worker in such a way as to make the invention obvious. That Hauske simply does not do. The only topical application Hauske talks about is in vitro, and Hauske never mentions applying anything to the eye.

Just as clearly, Bailey discloses nothing relating to topically applying azithromycin to the eye. Bailey summarizes the results of a randomised controlled trial of single dose azithromycin in the treatment of trachoma, but it is clear that no topical administration was involved. See the last sentence of the Introduction which states:

> "We carried out a randomised, single-blind study in two gambian villages to assess the effectiveness and safety of a single **oral** dose of 20 mg/kg azithromycin conventional treatment in ocular *C trachomatis* infection." [emphasis by bolding supplied]

In the second sentence of the second full paragraph of the left hand column on page 454 it is stated:

> Azithromycin suspension was made up as directed by the manufacturer (Pfizer, Sandwich, UK) and administered as a single dose (20 mg/kg) by mouth;

There is no disclosure or suggestion in Bailey of topically applying azithromycin to the eye. Clearly, the topical administration of azithromycin cannot be anticipated or obvious over a reference that discloses only systemic azithromycin administration, and which neither specifically discloses topical administration of azithromycin to the eye nor suggests anything about it.

The Thylefors article states that the conventional treatment for trachoma is 1% tertracycline eye ointment applied topically. When referring to azithromycin, Thylefors emphatically does not consider the possibility of topical eye application, however, stating in regard to azithromycin:

> "...it is rapidly and widely distributed throughout the body, and it shows markedly high concentrations in tissue as compared to plasma. Thus, the drug is heavily tissue-bound, with up to 150 times higher levels in some tissues in relation to plasma concentrations. [Page 133, left column]

The above discussion is consistent with a discussion of azithromycin administered systemically. It simply doesn't make sense to extract the idea of local (i.e., topical) administration from an article that talks about a drug being widely distributed throughout the body. For that reason it is submitted that Thylefors provides no

suggestion of topical azithromycin administration, let alone a specific disclosure. Accordingly, Thylefors neither anticipates the invention nor renders it obvious.

It is noted that the Examiner gave no weight to the recitation of topical application in Applicant's claims because the recitation occurs in the preamble. It is respectfully submitted that the preamble should be accorded weight in this case because, unless the preamble is held as limiting the claims, the claims would not properly identify the intended invention as set forth in the specification. See Corning Glass Works v Sumitomo,9 USPQ2d 1962, 1966 (Fed. Cir. 1989). As written, the claim is abundantly clear and the term "for topical application directly to the eye of an animal" is essential to point out the invention defined by the claim. It is respectfully submitted that the preamble would be included in any reasonable interpretation of the scope of the claims..

It is accordingly respectfully submitted that the rejections over Bailey, Thylefors, and Hauske, whether styled under section 102 or section 103, are not tenable, and it is requested that the rejections be withdrawn.

Claims 1-9 stand rejected under 35 USC 102(a) as anticipated by, or in the alternative, under 35 USC 103(a) as obvious over first meeting of the WHO Alliance For The Global Elimination of Trachoma, Geneva, 30 June 1997 (First Meeting). The examiner stated the claimed methods and compositions are anticipated by First Meeting). The Examiner also stated it would have been obvious to a person having ordinary skill in the art to combine azithromycin with conventional carriers for topical application.

The rejections are traversed on the basis that the reference, which does no more than express a desire or a wish, i.e., for a topical azithromycin formulation, does not support either anticipation or obviousness. First, it is well accepted that to be anticipatory, a reference must contain an enabling disclosure. Chester v. Miller, 15 USPQ 2d 1333 (Fed. Cir. 1990). First Meeting does not enable a topical azithromycin formulation, however. At the top of page 2, the publication states that no product is available and that efficacy and dosing schedule will need to be determined. At the top of page 3, first sentence, the reference states that a stable product must be developed. In the next sentence, First Meeting allows that an ophthalmic ointment would be simple to fabricate, but that "the problems of antibiotic ointment are well known." No formulations for topical azithromycin are disclosed, and no disclosure is given that would enable making such a formulation. First Meeting does no more than suggest that such a formulation would be nice to have, and then simply notes that no such formulation exists. First Meeting certainly fails to enable any topical eye formulation. Thus it is respectfully submitted that First

Meeting cannot anticipate Applicant, and it is respectfully requested that the anticipation rejection be withdrawn.

Second, it is well accepted that the prior art must not only provide a suggestion to do what the inventor has done, but musty also provide a reasonable expectation of succeeding in that endeavor. Both the suggestion and the expectation of success must be founded in the prior art, not in Applicant's disclosure. In re Dow Chemical, 5 USPQ2d, 1529 (Fed. Cir. 1988). First Meeting provides no such expectation of success, however. The reference in fact goes out of its way to point out that no stable product exists. Clearly First Meeting represents no more than an invitation to see whether a topical eye medicine is feasible, but with no realistic expectation that it will be. Only Applicant has provided the quality of disclosure which would allow one to make such a topical formulation. To premise a rejection on First Meeting is to use that which only the Applicant has taught against him. It is accordingly requested that the obviousness rejection over First Meeting be withdrawn.

In view of the foregoing comments it is respectfully submitted that this case is in condition for allowance. A notice of Allowance is courteously requested.

Respectfully submitted,

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